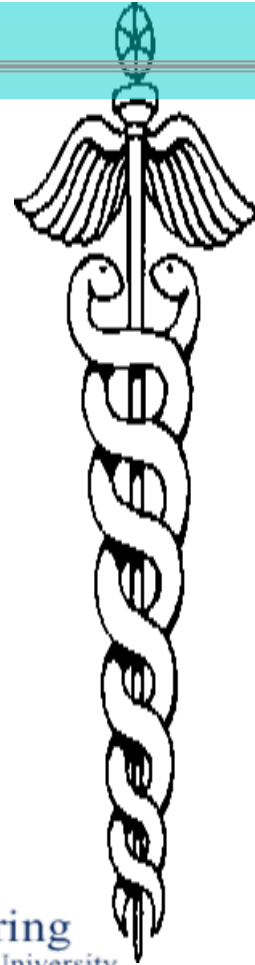
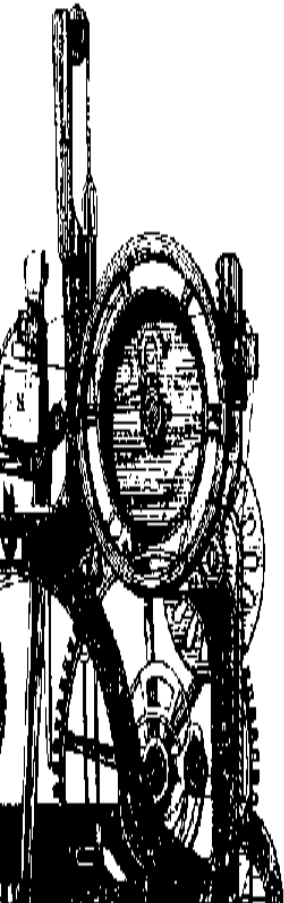


Impact of Pathways in the Business and Technological World



David Dilts PhD, MBA

Professor & Director, Engineering Management Program, School of Engineering

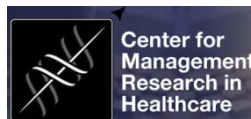
Professor & co-Director, Center for Management Research in Healthcare (www.cmrhc.org)

**Owen Graduate School of Management
Vanderbilt University**

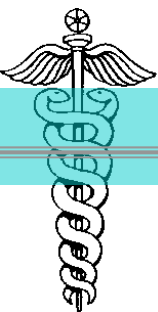
David.dilts@vanderbilt.edu



VANDERBILT UNIVERSITY
OWEN GRADUATE SCHOOL OF MANAGEMENT



School of Engineering
Vanderbilt University



Differing Views

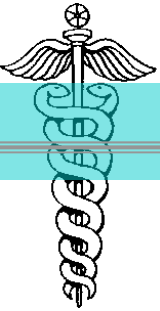


- When someone says “I read it in the journal” what journal do you think of?



How would a biologist fix a customer's broken radio?

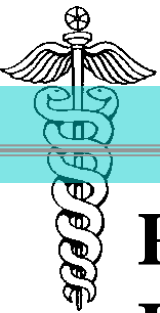
Idea adapted from : Lazebnik Y, "Can a biologist fix a radio?", *Cancer Cell*, Sept 2002, 2:179-182



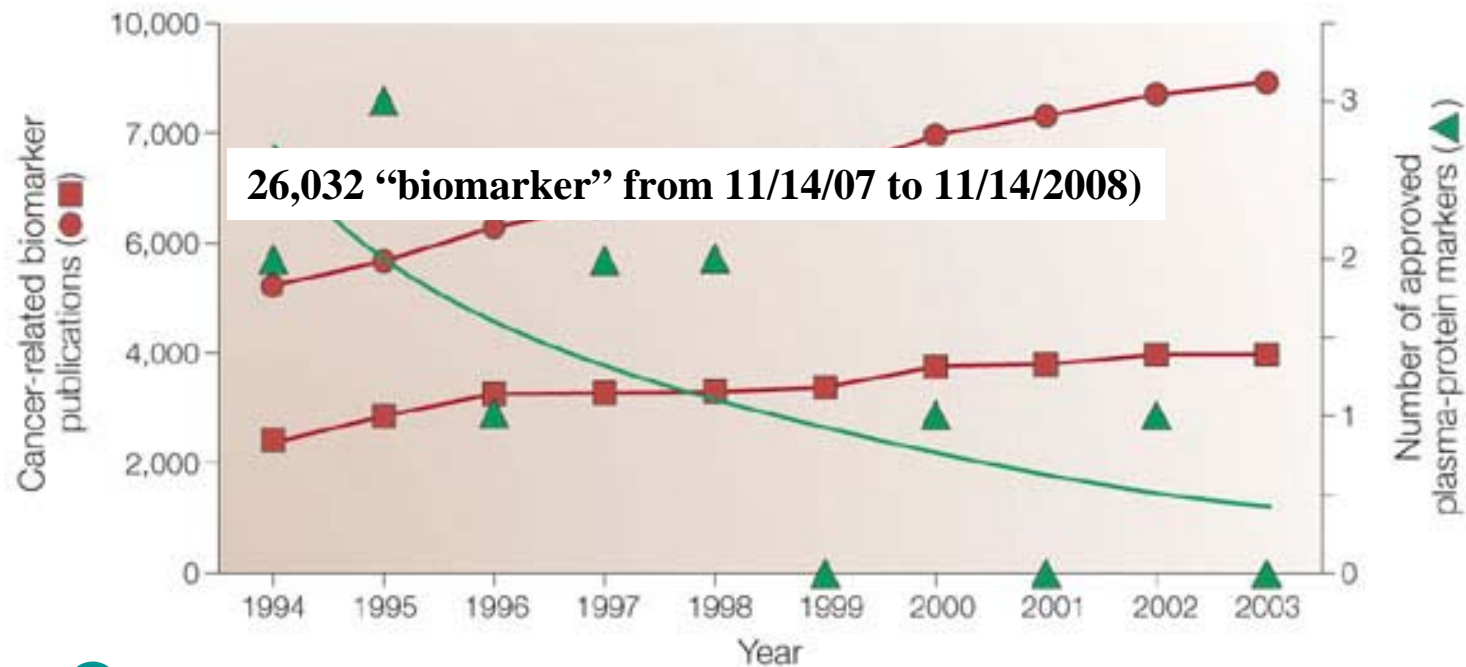
Question: what does the customer think?

1. Write grant to secure funds to obtain a large supply of identically broken radios
2. After 2-3 rounds of grant reviews, buy the radios, hire techs & get the lab
3. Have the techs hit the radios with a hammer until they (radios, not techs) stop working and disassemble them
4. Write papers on how many hits it takes to stop working, shape of broken pieces, etc.
5. Apply for more research funding because you are out of money

If you were in Congress, what would you think of this?



Publications on Biomarkers and FDA Approval of Biomarkers (Ludwig JA; Weinstein JN *Nature Rev. Cancer* 2005 (5):845-56)

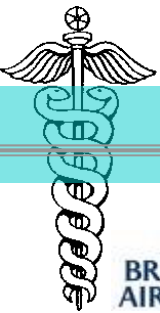


- - Medline text word “biomarker”
- - Medline subject heading “biomarker”
- ▲ - FDA Approved markers

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Nature Reviews | Cancer

From roses to rockets From cars to cancer



BRITISH
AIRWAYS



Primary Research Questions

How to integrate diverse systems?

Or how do you put the pieces together?

How to transfer lessons learned between domains?

Or, what can we learn, both good & bad, from others?

DAIMLERCHRYSLER

OAK RIDGE NATIONAL LABORATORY

Managed by UT Battelle for the Department of Energy



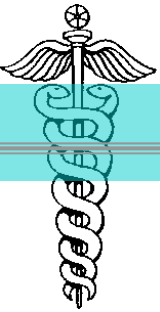
© David M. Dilts, PhD



LAWRENCE LIVERMORE NATIONAL LABORATORY
Science in the National Interest

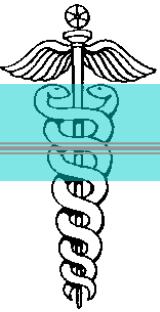


Basic Lessons Learned



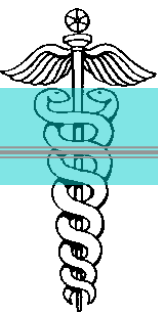
1. Expectations and environments change constantly
2. There is never enough money or resources
 - So they need to be used wisely
 - Priorities will be set
 - The only question is: will you help set them?
3. Using a pathway can make life easier
 - Good pathways/processes can show you things you never expected & can be trend setting
 - *But pathways are living documents that can grow in unexpected ways*
4. Use experts when every possible but remember: they don't know your domain

Basic Lessons Learned



1. Expectations and environments change constantly

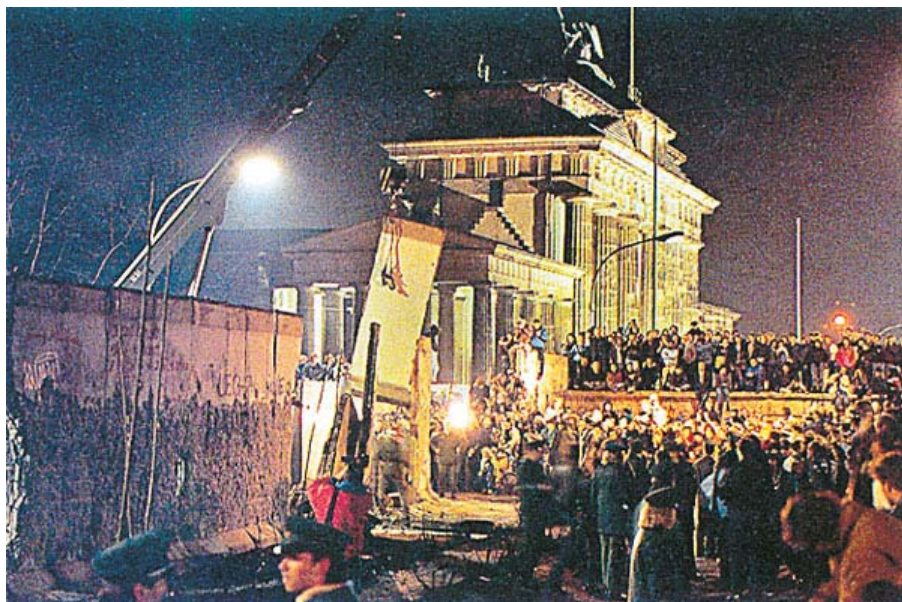




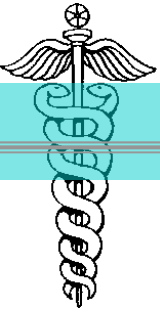
Two Examples



1. DOE Labs and “winning the cold war”
 - 1989 tearing down of the Berlin Wall



2. Oldsmobile



1897 — Founded by Ransom Eli Olds

One of the first US auto manufacturers

1901 — Introduced the assembly line & becomes the first mass manufacturer of gasoline powered automobiles

The first:

- **Mass-produced automobile (Oldsmobile Curved Dash, 1901)**
- **Motor vehicles used by US Post Office**
- **To have a**
 - **Speedometer (1901)**
 - **Automatic choke (1932)**
 - **Automatic transmission (hydra-matic, 1939)**
 - **Overhead Valve V8 (1949)**
 - **Airbags (1974)**




1976 — Produced American's best selling car (*Olds Cutlass*)

2004 — Final production of Oldsmobile

Remember When (1970's)



Now you can step up to
an Olds priced under \$5,000.
Even good gas economy comes standard.




OMEGA: The Looks.
Who says an "economy" car has to look like an economy car? This one's an Oldsmobile—and looks it!

The Price: \$4,194*
Makes a lot of "economy" cars look over-priced.

The Mileage:
26 mpg highway, 19 city.
EPA estimates with standard 231 V-6 and available automatic transmission. EPA estimates are lower in California. Your mileage will vary depending on how you drive, your car's condition, and its equipment.

The Equipment You Want.
The price shown includes automatic transmission, AM radio, belted bias-ply white-wall tires, body side striping and chrome wheel discs.



CUTLASS: The Looks.
Cutlass style and Cutlass comfort—with your choice of cloth or vinyl-trimmed seats.

The Price: \$4,811*
Making this the most affordable Cutlass going.

The Mileage:
25 mpg highway, 17 city.
EPA estimates with standard 231 V-6 and available automatic transmission. EPA estimates are lower in California. Your mileage will vary depending on how you drive, your car's condition, and its equipment.

The Equipment You Want.
The price shown includes automatic transmission, AM radio, glass-belted radial white-wall tires, body side striping and chrome wheel discs.

*Manufacturer's suggested retail price, including dealer preparation. Tax, license, destination charges, and other available equipment additional.

Oldsmobile
Can we build one for you?

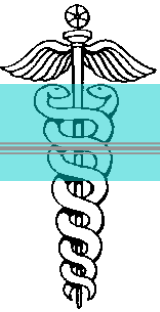


1970 Corvette Stingray

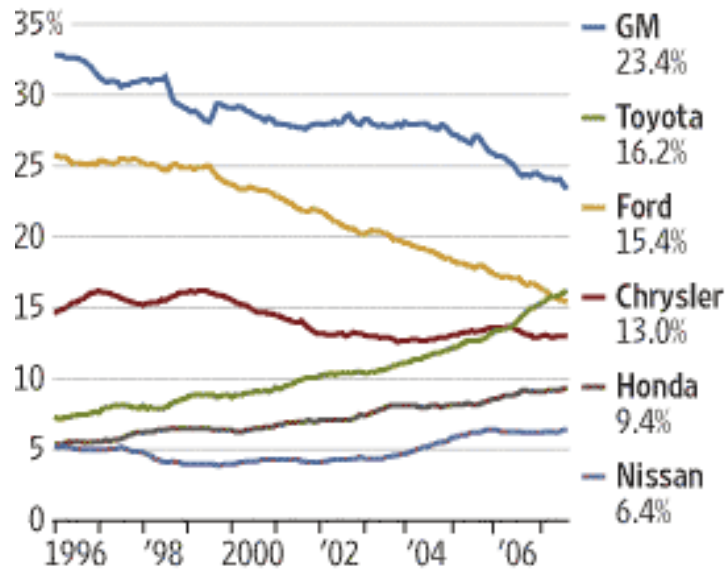


1970 Toyota Carina

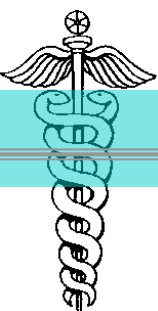
What's Happened Since?



U.S. Market Share 12 Month Moving Average



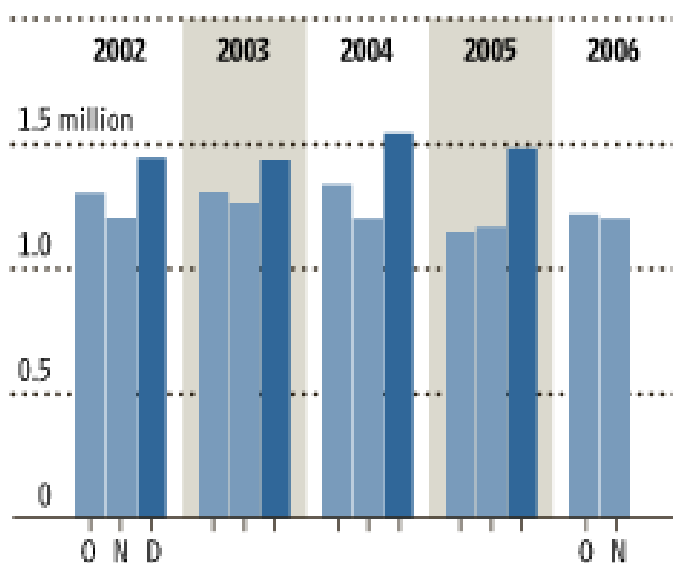
McCracken, J "In shift, Auto Workers flee to health-care jobs" WSJ, 9/11/2007, pg A1.
<http://online.wsj.com/article/SB118947456678423358.html>



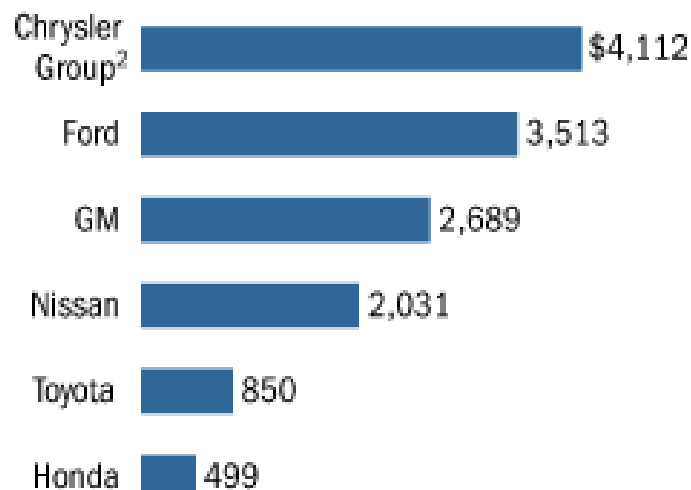
Christmas Cruising

Auto makers typically offer incentives in December to clear out old models and gin up holiday excitement on new ones.

Monthly U.S. vehicle sales, fourth quarter



Average cost of incentives¹ per vehicle, November

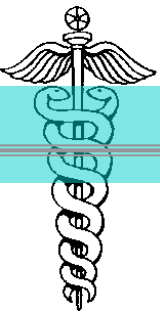


¹Takes into account all U.S. incentive programs, including subvented interest rates and lease programs as well as cash rebates to consumers and dealers. Customers should check with local dealers for specific information. ²Chrysler excluding Mercedes

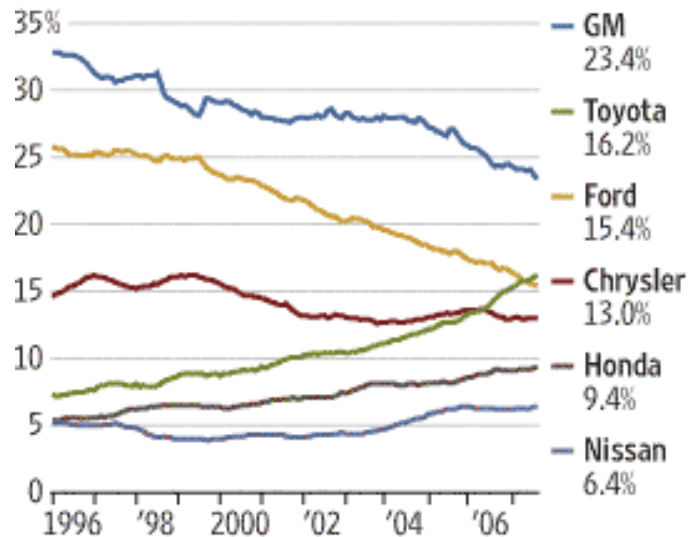
Sources: Autodata; Edmunds.com

Source: Specter M, "Honey, You Shouldn't Have," WSJ, 2006-12-19 B1

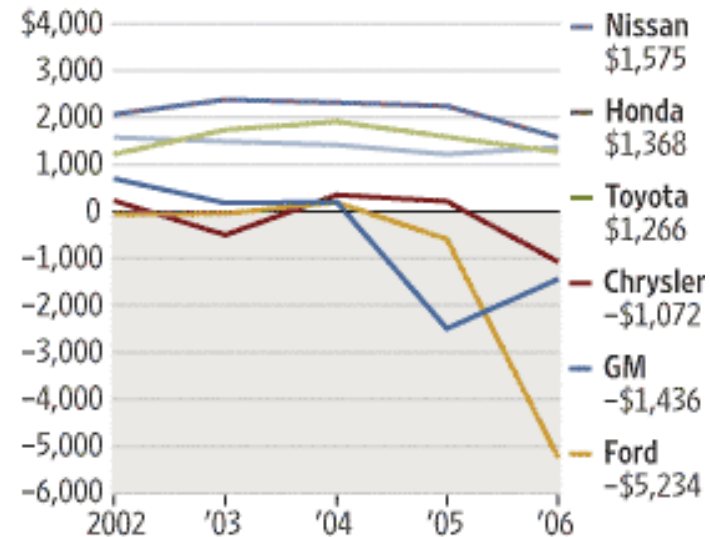
What's Happened Since?



U.S. Market Share
12 Month Moving Average



Pretax profit or loss per vehicle
Manufactured in North America

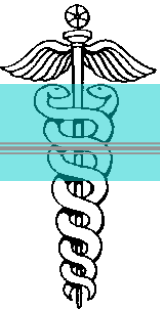





Note: Pretax profit/loss data for U.S. auto makers are for calendar years; data for Japanese auto makers, fiscal years
Source: Autodata (market share); Harbour Consulting (profit/loss)

McCracken, J "In shift, Auto Workers flee to health-care jobs" WSJ, 9/11/2007, pg A1.
<http://online.wsj.com/article/SB118947456678423358.html>

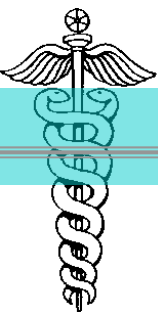
3rd Quarter Numbers

November 7, 2008



- **Ford** 
 - **\$0.13 billion loss** Burn rate: \$7.7 billion
- **GM** 
 - **\$2.54 billion loss** Burn rate \$6.9 billion
- **Per Hour Numbers:**
 - GM has **lost \$2.13 million/hr** every hour for the past 3 ³/₄ years (\$70 billion in total)
 - GM & Ford — burning **\$6.7 million/hr**
- **Toyota** 
 - **“only” posted a net profit of \$1.4 billion**

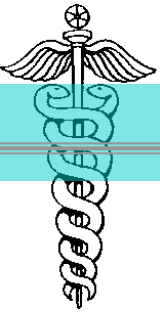




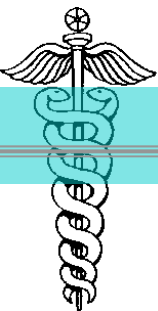
Lessons to Learn:

- What was good yesterday, might not be good today
- What was bad yesterday is even worse today

Basic Lessons Learned



1. Expectations and environments change constantly
2. There is never enough money or resources
 - So they need to be used wisely
 - Priorities will be set, the only question is
 - Will you help set them?



EDUCATION | OCTOBER 2, 2008

Colleges Scramble as Fund Is Frozen

Some 1,000 Schools Find It May Take Years To Recover Money Placed With Wachovia

By JOHN HECHINGER and CRAIG KARMIN



A fund that invests cash for about 1,000 colleges and private schools suddenly froze withdrawals this week, leaving school finance managers scrambling to make sure they have enough money for payroll and other bills.

For 34 years, colleges and schools parked cash in the now \$9.3 billion fund, which offered returns slightly above U.S. Treasury bills. That it now might take years for the institutions to get all of their money back shows how widely credit-market woes are reverberating beyond Wall Street.

Monday, [Wachovia Corp.](#), the fund's trustee, said it was terminating the fund, liquidating its assets, distributing the proceeds and resigning as trustee, "to ensure that all investors would get equal treatment and that there would be orderly and equal distributions," says Laura Fay, a Wachovia spokeswoman. That stunned some of the colleges, which had believed they could get immediate access to the money if needed.

October 1, 2008

Even Healthy Retailers Fear Loss of Credit Lifeline

By [KEN BELSON](#)

For the past year, New Yorkers have largely felt apart from the economic turmoil enveloping other parts of the country. But businesses in and around the city have reason to fret, now that banks are becoming more tightfisted during the deepening crisis in credit markets worldwide.

Small businesses often live at the mercy of their creditors. When times are good, loans are easy to get. When business sours, loans can dry up. With banks handing out fewer loans and raising interest rates, even healthy businesses are becoming worried that they will not get the credit they need to keep their doors open and their bills paid.

His nightmare involves the bank's freezing his credit line, which he uses to pay for food and beverage deliveries, repairing equipment and fixing his store.

"It could happen any week, or any day — you never know," said Mr. McKenna, who said sales fell 20 percent in August, the worst performance in the three years since he took over the shop. "If you don't have a line of credit, it could kill you."

The banking industry's problems hit retail businesses twice, because their customers also rely on credit to buy big-ticket items like computers, flat-panel televisions and home furnishing.



Feeling the Pinch New signals that the economy may be nearing recession:



U.S. light-vehicle sales, change from a year earlier in the 12-month moving average



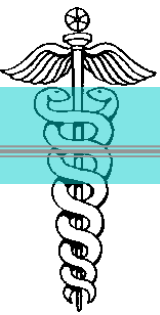
Manufacturing activity, based on ISM index; below 50 signals a contraction



U.S. construction spending, year-to-year change

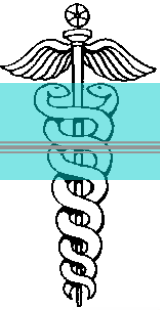


Source: AutoData (vehicle sales); Institute for Supply Management (manufacturing activity); U.S. Census Bureau (construction spending)



Reddy, S "Fed considers rate cut as recession fears mount," WSJ 2008-10-02

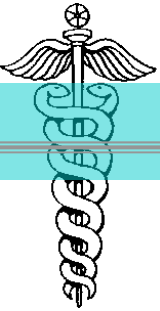
So, in an era of massive, unprecedented demands



Who do you think will get the money?

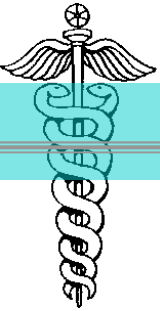


So,

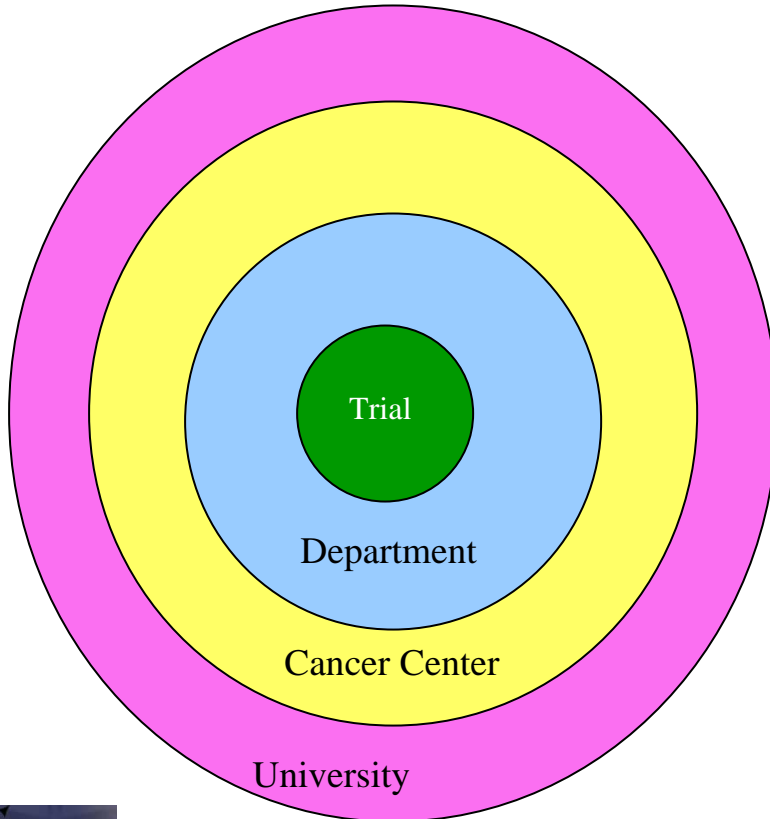


- In, an era of massive budget cuts and increased need, whose research should be funded?
- **MINE!**

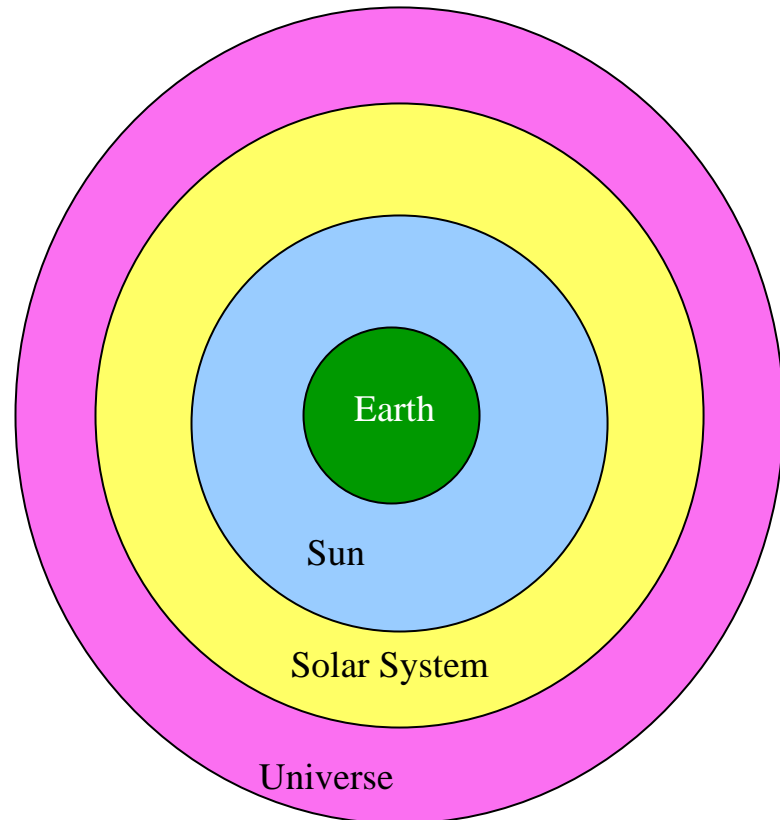
A PI's View



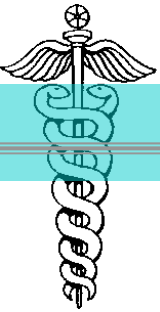
How PI's view the world...



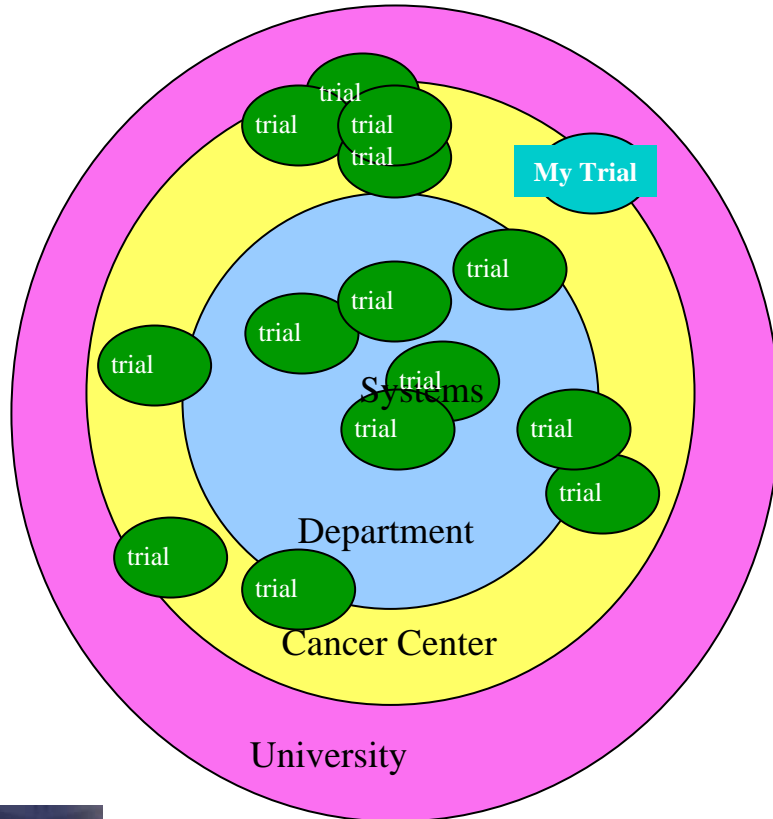
...is how we use to view the universe.



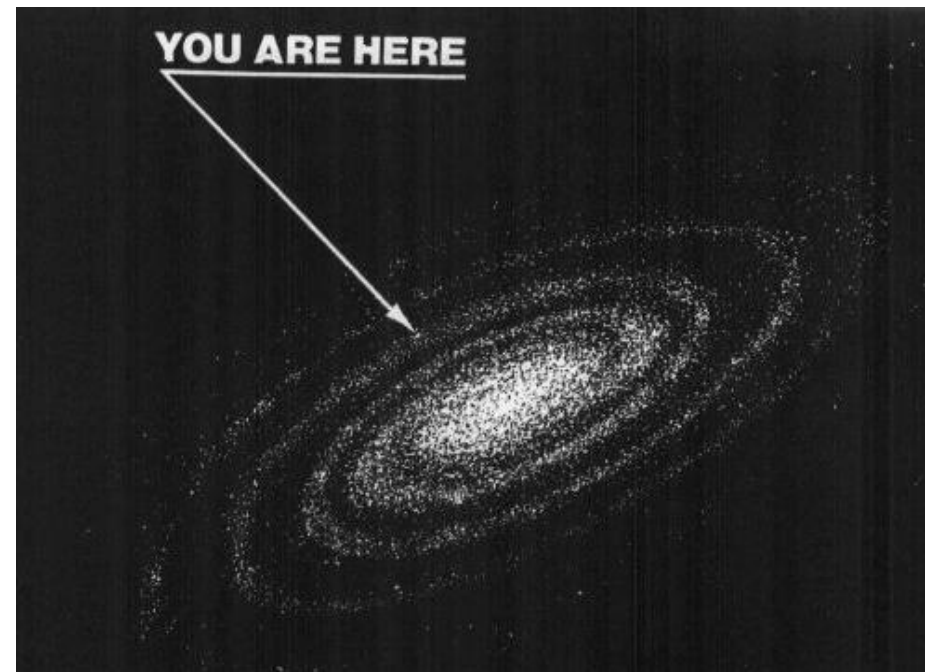
A More Global View



**How the NCI views
the trial...**



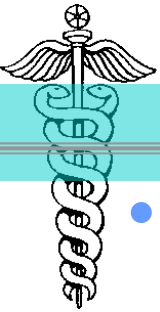
**...is how we now view the
Universe.**



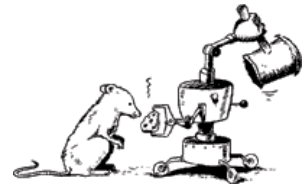
(the arrow points to our star, 1 of 200 billion stars, in 1
galaxy of 100 billion galaxies)



“Make a Better Mousetrap ...”

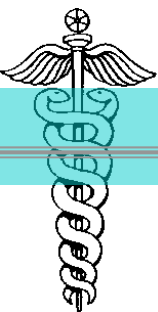


- The Full Quote:
 - *“If a man can write a better book, preach a better sermon, or make a better mouse-trap, than his neighbor, though he build his house in the woods, the world will make a beaten path to his door.”*
 - Ralph Waldo Emerson 1871.
- How many kinds of mouse traps can you think of?
- When was the best selling mouse trap created?
- How many patents have been given for mouse traps since 1976?
- Answers:
 - Spring, glue, box, electronic, etc.
 - 1924 by Kness
 - 329 as of yesterday from the Patent Office Web site



Same Idea: “If you build it, they will come”





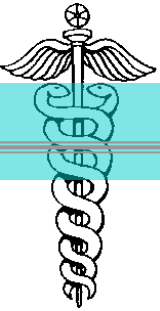
So, “no” has to be said



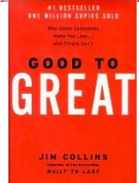
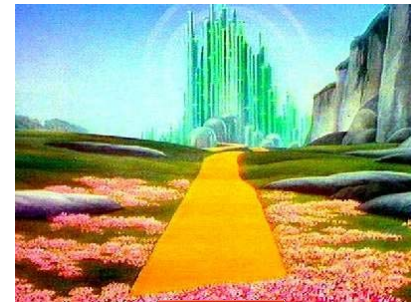
“A ‘No’ uttered from deepest conviction is better and greater than a ‘Yes’ merely uttered to please, or what is worse, to avoid trouble.”

--- Mahatma Gandhi

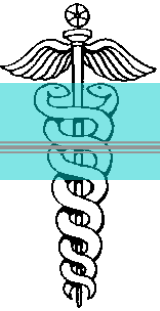
Ideas for Rules for Identifying Priorities



- **Focus on your strengths**
 - *Not problems*
- **Concentrate on the future,**
 - *Not the past*
- **Choose your own spot on the pathway,**
 - *Not what others do*
- **Aim high,**
 - *Not safe & easy*
 - *BHAG* (“Good to Great” Jim Collins)
- **Get the right people “on the bus”**



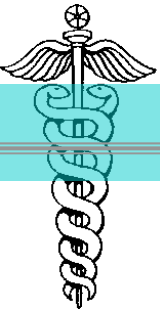
Remember



“A rising tide raises all boats”



Basic Lessons Learned



1. Expectations and environments change constantly
2. There is never enough money or resources
 - So they need to be used wisely
 - Priorities will be set
3. Using a pathway can make life easier
 - Good pathways/processes can show you things you never expected & can be trend setting
 - *But pathways are living documents that can grow in unexpected ways*



The flowchart illustrates the drug development process, categorized by stages on the left and color-coded by activity on the right.

Stages (Left):

- Credentiaiting
- Supporting tools
- Creation of modality
- Precinical development
- Clinical trials

Activity Legend (Right):

- Credentiaiting (Blue)
- Supporting tools (Pink)
- Creation of modality (Green)
- Precinical development (Purple)
- Clinical trials (Yellow)

Flowchart Steps:

- Fundamental research (Supporting tools)
- Discovery with potential clinical application (Credentiaiting)
- Decision: Is the empirical basis for attributing clinical relevance convincing? (scientific validation) (Credentiaiting)
 - If no: Redirect research effort elsewhere (Credentiaiting)
 - If yes: Proceed to next step.
- Decision: Does the envisioned clinical need justify expenditure or resources? (Credentiaiting)
 - If no: Redirect research effort elsewhere (Credentiaiting)
 - If yes: Proceed to next step.
- Decision: Is development process likely to be feasible? (Credentiaiting)
 - If no: Redirect research effort elsewhere (Credentiaiting)
 - If yes: Proceed to next step.
- Develop modality (Creation of modality)
- Decision: Efficacy justifies continued development? (Creation of modality)
 - If no: Redirect research effort elsewhere (Credentiaiting)
 - If yes: Proceed to next step.
- Refine modality for efficacy (Creation of modality)
- Refine for safety/ manufacturability/ deployability (Precinical development)
- Decision: Applicable standards met? (Precinical development)
 - If no: Can it be fixed? (Precinical development)
 - If yes: Refine for safety/ manufacturability/ deployability (Precinical development)
 - If no: Redirect research effort elsewhere (Credentiaiting)
 - If yes: Proceed to next step.
- Early-stage clinical trials (Clinical trials)
- Supporting tools (Pink): Develop required supporting tools or systems
 - Assess target effects (Supporting tools)
 - Identify cohort that would benefit (Supporting tools)

-
- ```

graph TD
 A[Fundamental research] --> B[Discovery of antigen or other immune modifier with clinical potential in specific cancers]
 B --> C{Is the animal basis for adjuvanting clinical potential convincing? (Established immune modifier)}
 C -- no --> D[Refined research start elsewhere]
 C -- yes --> E{Does envisioned clinical need justify expenditure of resources?}
 E -- no --> D
 E -- yes --> F{Is it feasible to identify/develop the immune response modifier?}
 F -- no --> D
 F -- yes --> G[Identify or develop clinically relevant self culture system and/or animal model]
 F -- yes --> H[Identify or develop immunomodulatory adjuvant (vaccine, cell, etc.)]
 H --> I[Develop immune response modifier]
 I --> J[Measure response to immune response modifier]
 J --> K{Activity sufficient to warrant continued development?}
 K -- no --> L[Refine antigen(s)]
 L --> I
 K -- yes --> M[Refine delivery vehicle(s)]
 M --> N[Refine immune modulator(s)]
 N --> O[Refine immune response modifier and/or immunisation strategy]
 O --> P[Measure response to immune response modifier]
 P --> Q{Activity sufficient to warrant continued development?}
 Q -- no --> R{Can it be toxic?}
 R -- yes --> S{Can it be toxic?}
 R -- no --> T{Can it be toxic?}
 S -- yes --> U[Can it be toxic?]
 S -- no --> V[Can it be toxic?]
 T -- yes --> W[Can it be toxic?]
 T -- no --> X[Can it be toxic?]
 U -- yes --> Y[Can it be toxic?]
 U -- no --> Z[Can it be toxic?]
 V -- yes --> AA[Can it be toxic?]
 V -- no --> AB[Can it be toxic?]
 W -- yes --> AC[Can it be toxic?]
 W -- no --> AD[Can it be toxic?]
 X -- yes --> AE[Can it be toxic?]
 X -- no --> AF[Can it be toxic?]
 Y -- yes --> AG[Can it be toxic?]
 Y -- no --> AH[Can it be toxic?]
 Z -- yes --> AI[Can it be toxic?]
 Z -- no --> AJ[Can it be toxic?]
 AA -- yes --> AK[Can it be toxic?]
 AA -- no --> AL[Can it be toxic?]
 AC -- yes --> AM[Can it be toxic?]
 AC -- no --> AN[Can it be toxic?]
 AD -- yes --> AO[Can it be toxic?]
 AD -- no --> AP[Can it be toxic?]
 AE -- yes --> AQ[Can it be toxic?]
 AE -- no --> AR[Can it be toxic?]
 AF -- yes --> AS[Can it be toxic?]
 AF -- no --> AT[Can it be toxic?]
 AG -- yes --> AU[Can it be toxic?]
 AG -- no --> AV[Can it be toxic?]
 AH -- yes --> AW[Can it be toxic?]
 AH -- no --> AX[Can it be toxic?]
 AI -- yes --> AY[Can it be toxic?]
 AI -- no --> AZ[Can it be toxic?]
 AJ -- yes --> BA[Can it be toxic?]
 AJ -- no --> BB[Can it be toxic?]
 AK -- yes --> BC[Can it be toxic?]
 AK -- no --> BD[Can it be toxic?]
 AL -- yes --> BE[Can it be toxic?]
 AL -- no --> BF[Can it be toxic?]
 AM -- yes --> BG[Can it be toxic?]
 AM -- no --> BH[Can it be toxic?]
 AN -- yes --> BI[Can it be toxic?]
 AN -- no --> BJ[Can it be toxic?]
 AO -- yes --> BK[Can it be toxic?]
 AO -- no --> BL[Can it be toxic?]
 AP -- yes --> BM[Can it be toxic?]
 AP -- no --> BN[Can it be toxic?]
 AQ -- yes --> BO[Can it be toxic?]
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 DF -- no --> GT[Can it be toxic?]
 DG -- yes --> GU[Can it be toxic?]
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 DH -- no --> GX[Can it be toxic?]
 DI -- yes
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# Lots of Other Models

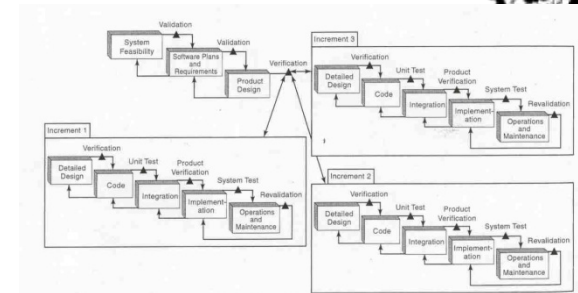
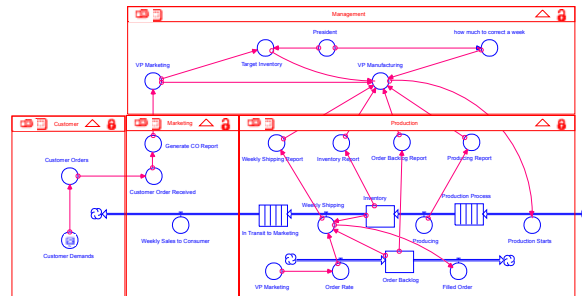
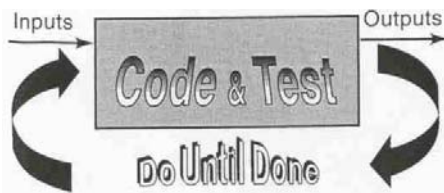
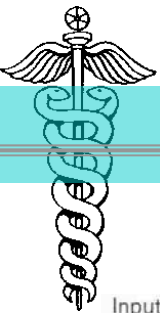


FIGURE 4-13  
The Incremental Model

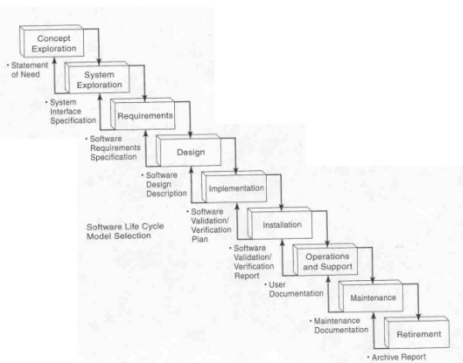


FIGURE 4-1  
Selection of a Project-Specific Life Cycle Occurs at the Beginning of the Project

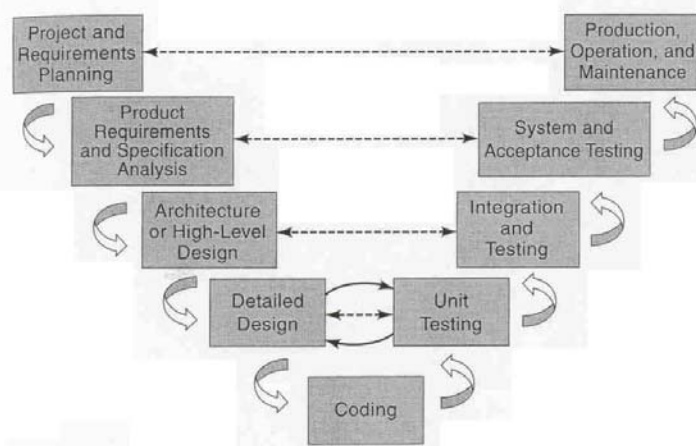


FIGURE 4-10  
The V-Shaped Software Development Life Cycle Model

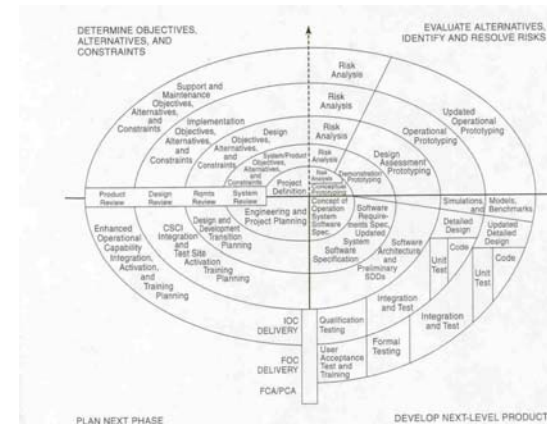
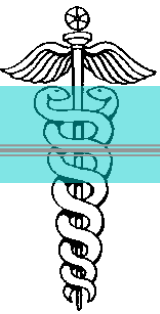
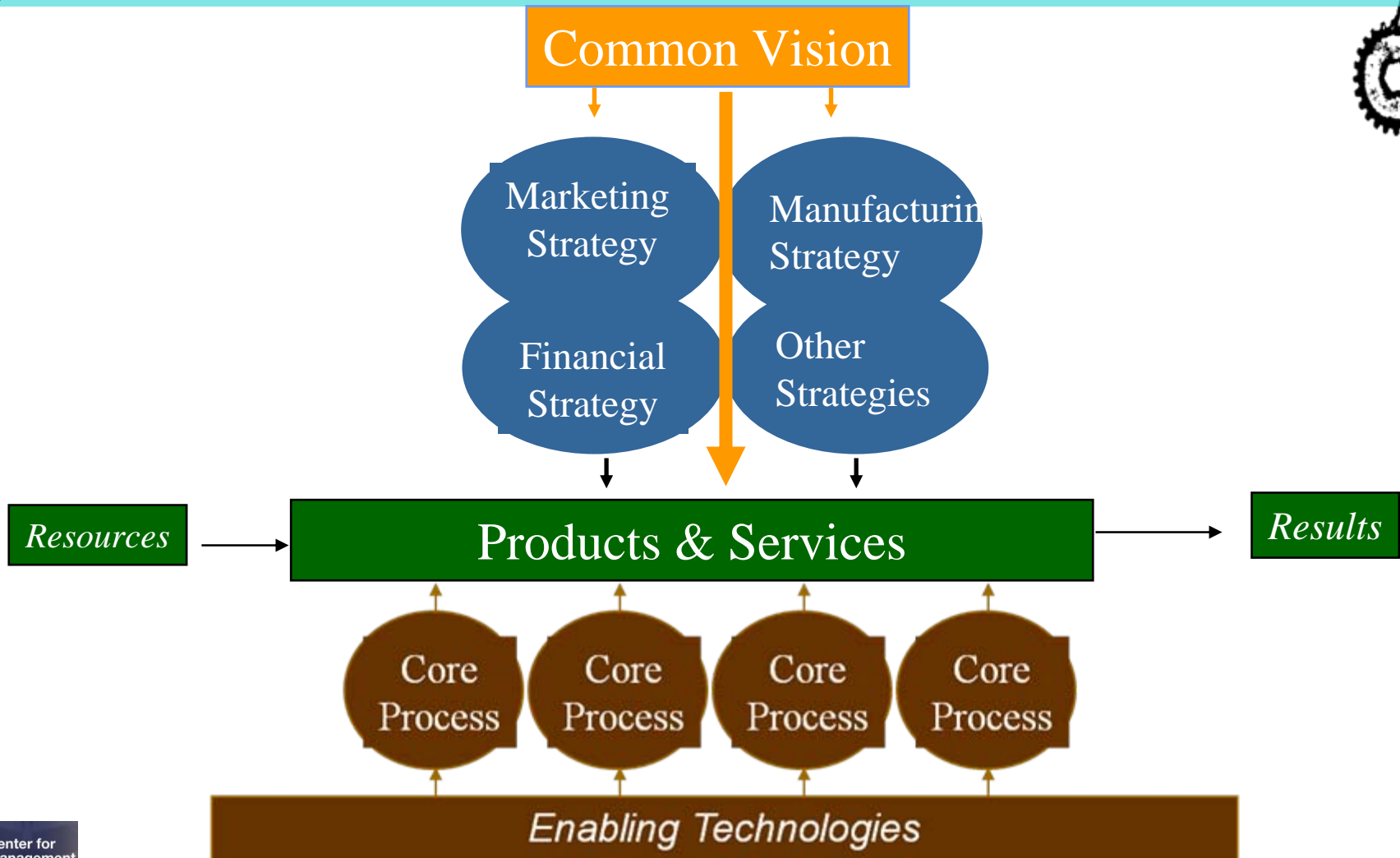
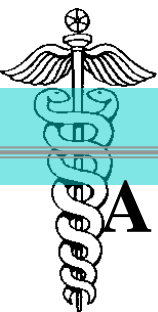


FIGURE 4-14  
The Spiral Model

# An Integrated Enterprise Approach

Source: David Dilts, (1993) CAM-I Competitively Integrated Enterprise, Vol. I.

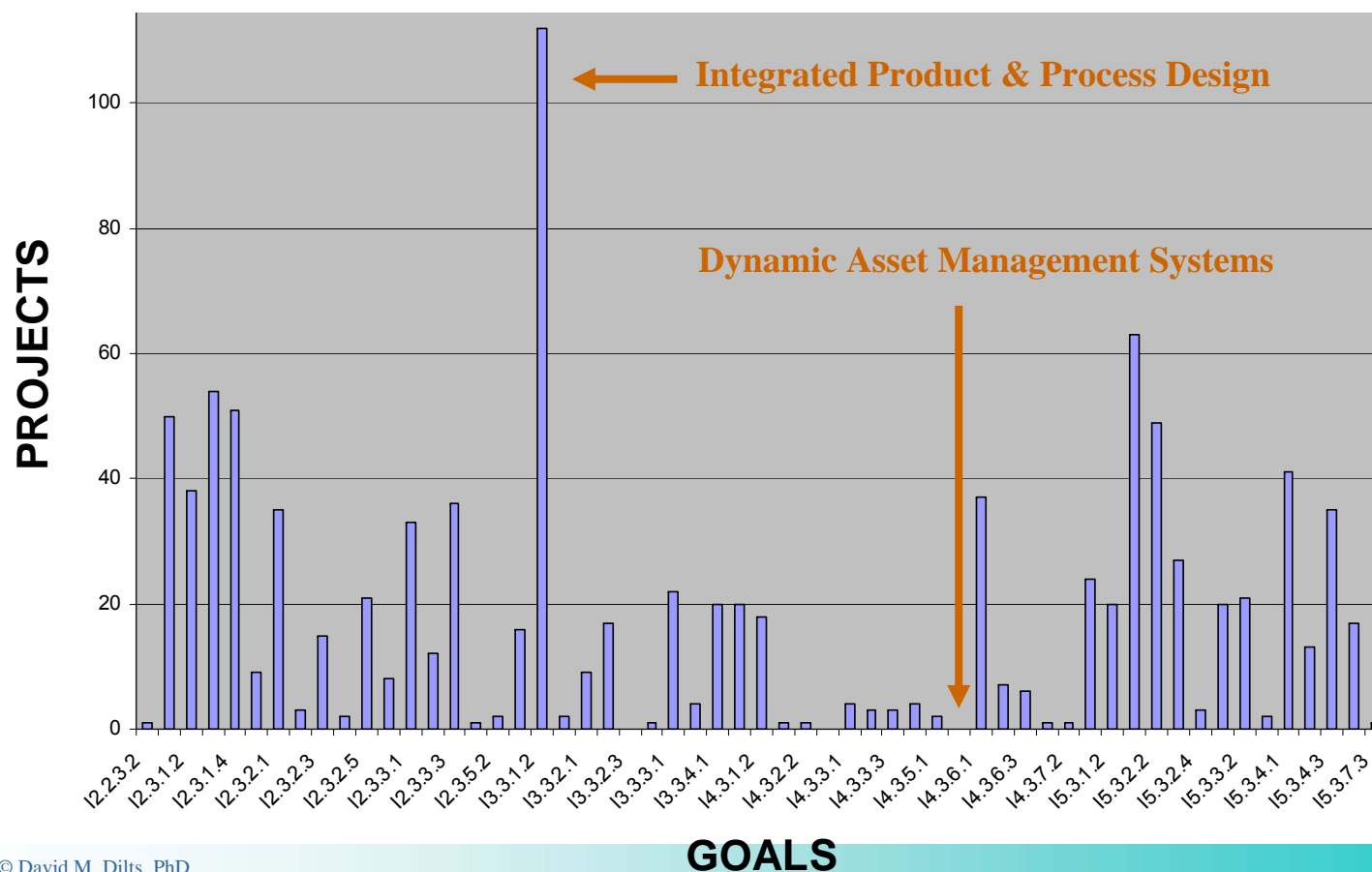


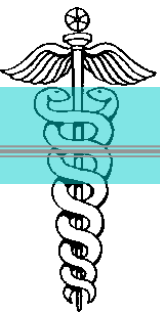


# IMTR Gap Analysis



A comparison of government-sponsored research projects versus industry-stated goals in research



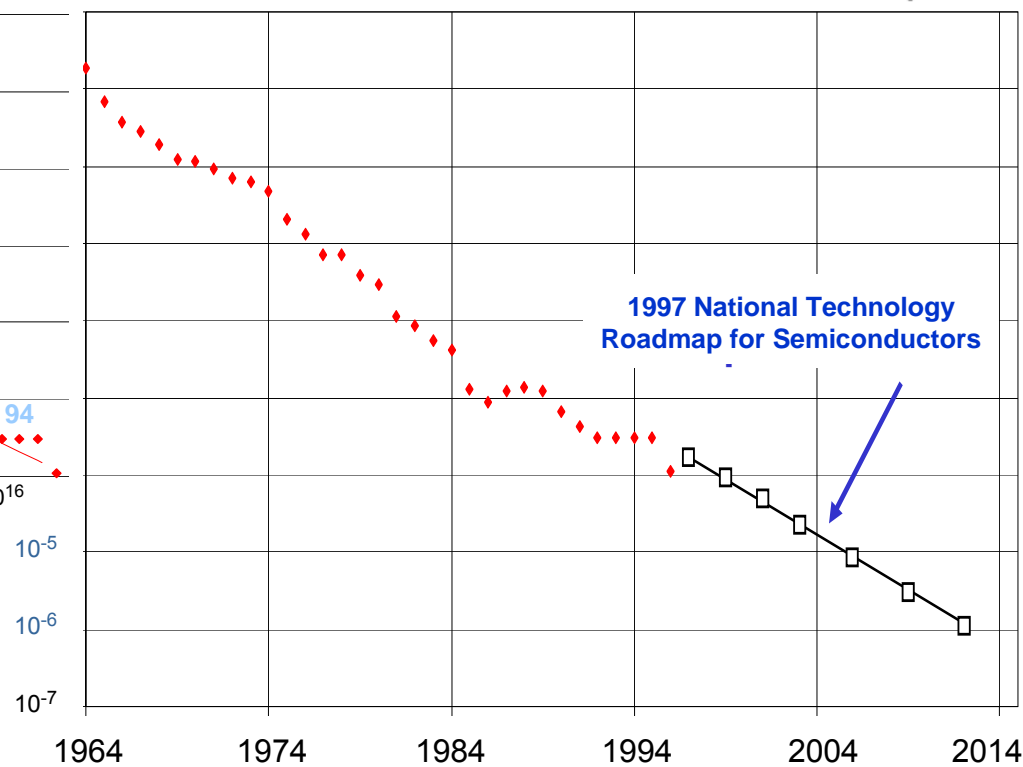
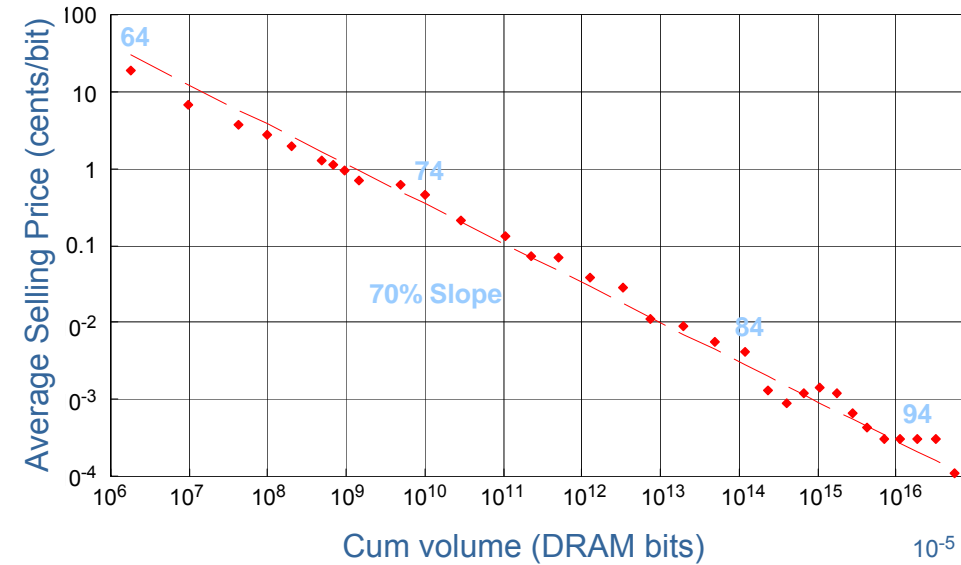


# Semiconductor Memory (DRAM)



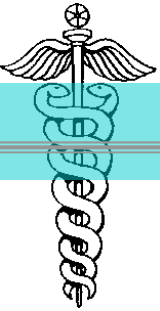
Experience Curve

Time Trend



“Moore’s Law”

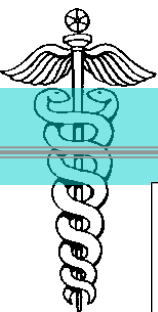
# Why Roadmaps for Integration?



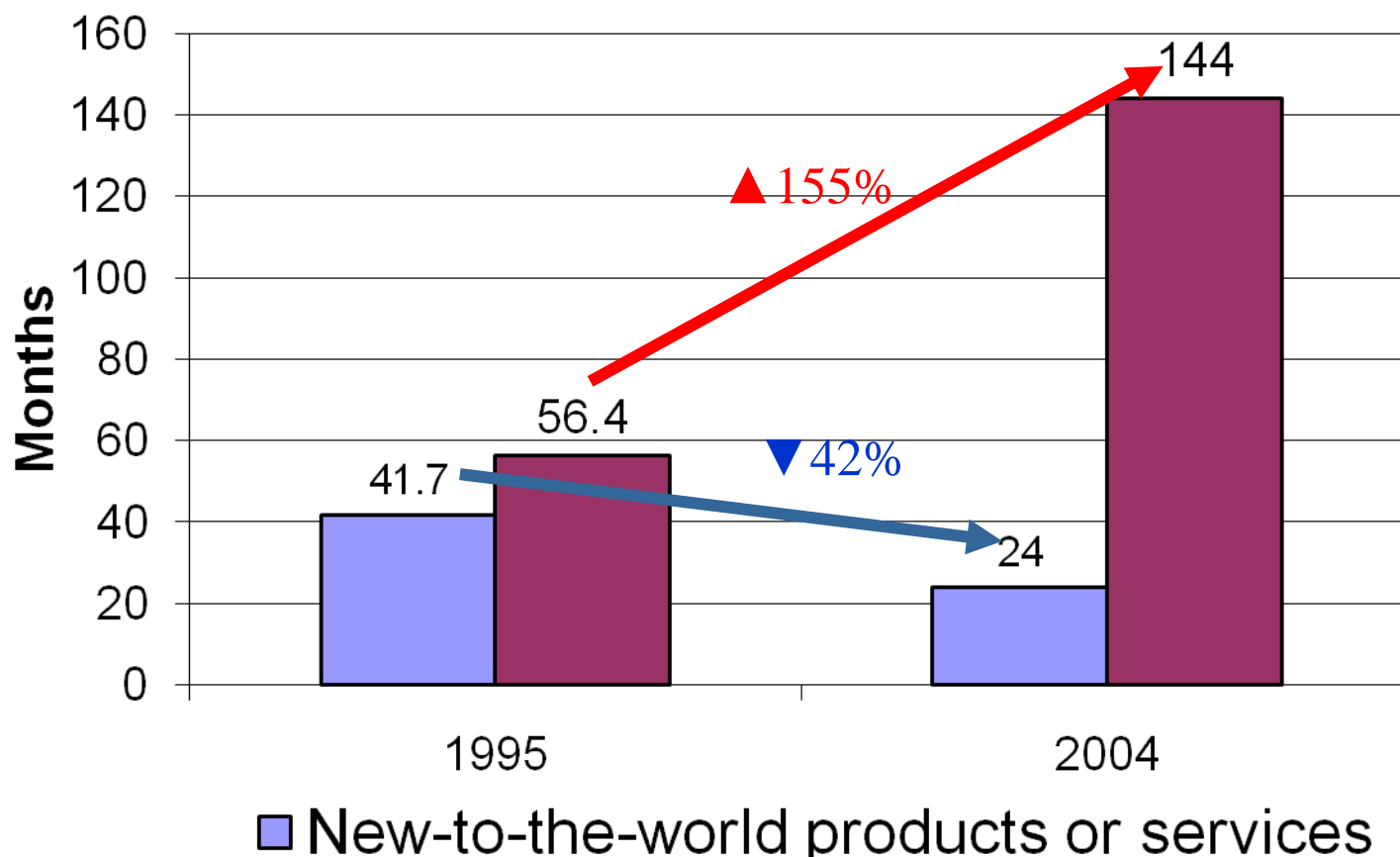
Source: David Dilts, (1993) CAM-I Competitively Integrated Enterprise, Vol. I.



- *Allen-Bradley*: 80% reduction in order-to-shipment time; 250% increase in shipments
- *Deere & Company*: 60% reduction in overhead; 30–50% reduction in time to market
- *DEC*: 50% reduction in new product development time
- *HP*: 50% reduction in direct labor cost; 73% reduction in handling cost
- *Northern Telecom*: 75% reduction in order-to-delivery time
- *TI*: 22.5-fold increase in production volume
- *Westinghouse*: 85% reduction in manufacturing cycle time

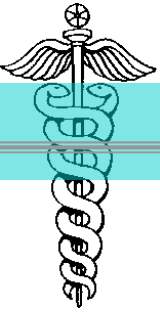


# Development Time in General



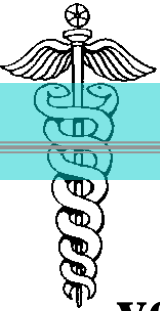
- Adams M, Boike D. Product Development and Management Association Foundation's Comparative Performance Assessment Study: PDMA Foundation; 2004;
- Slater EE. Today's FDA. N Engl J Med 2005;352:293-7.

# When functional areas don't “Fit”





# What happens if you get it wrong? Airbus A380

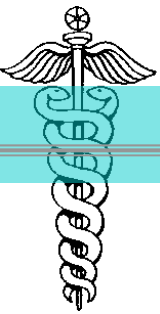


... A380 superjumbo would be delayed by at least two years. The delay and resulting changes to the program were expected to cost ... as much as **\$6 billion in lost profits...**

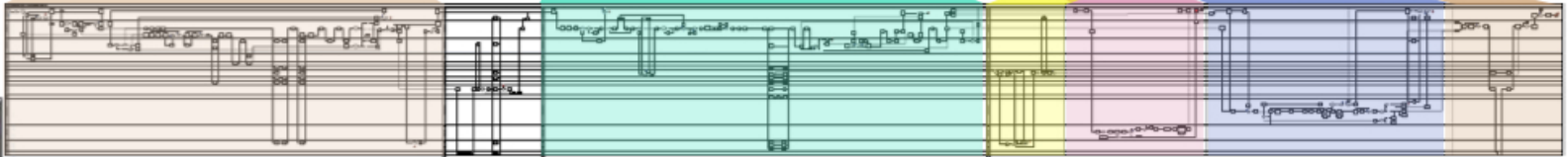
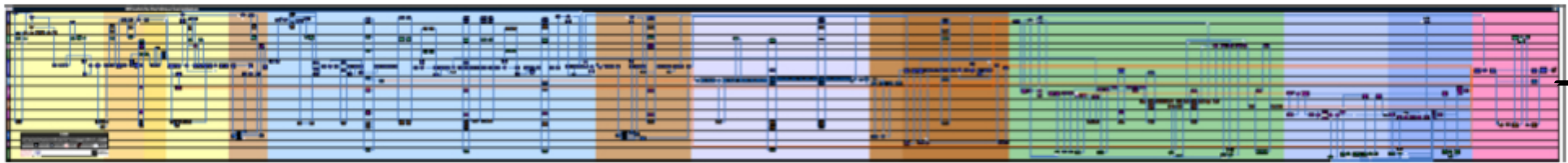
When the first wiring bundles ... began arriving at the assembly plant in Toulouse last June, they didn't fit properly from the rear section into the front section of the fuselage. Workers tried to pull the bundles apart and feed the wiring through the fuselage by hand, but with **300 miles of wire and some 40,300 connectors on each plane**, the immensity of the problem soon became obvious.

Airbus engineers in Germany, ..., were using an older version of Dassault Systèmes' Catia computer-aided design software—**version 4**. Engineers in Toulouse, France, ... were using a newer version of the software, **Catia V5**.

# Opening a Phase III Cooperative Group Trial at a CCC



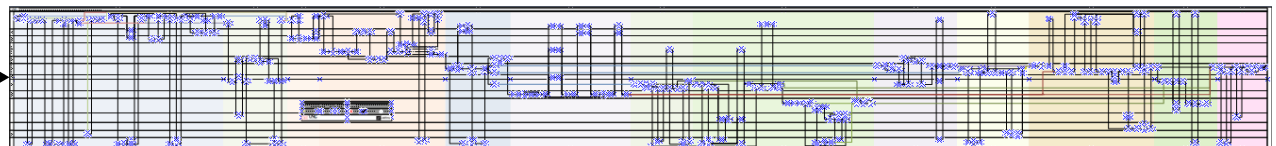
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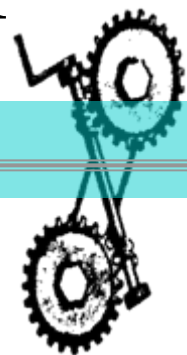
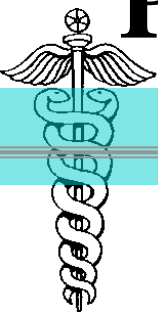
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CCC

37'1" x 3'6" ft in 8pt font



# Process Steps for Opening a Phase III Cooperative Group Trial<sup>1</sup>

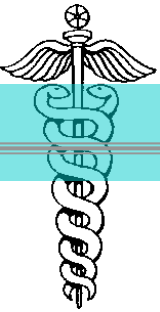


|                                    | Cooperative Group | CTEP /CIRB     | CCC            | Total          |
|------------------------------------|-------------------|----------------|----------------|----------------|
| <b>Process Steps</b>               | <b>&gt;458</b>    | <b>&gt;216</b> | <b>&gt;136</b> | <b>&gt;810</b> |
| <b>...Working Steps</b>            | <b>&gt;399</b>    | <b>&gt;179</b> | <b>&gt;74</b>  | <b>&gt;652</b> |
| <b>...Decision Points</b>          | <b>59</b>         | <b>37</b>      | <b>62</b>      | <b>158</b>     |
| <b>Potential Loops<sup>2</sup></b> | <b>26</b>         | <b>15</b>      | <b>27</b>      | <b>68</b>      |
| <b>No. of Groups Involved</b>      | <b>11</b>         | <b>14</b>      | <b>13</b>      | <b>38</b>      |

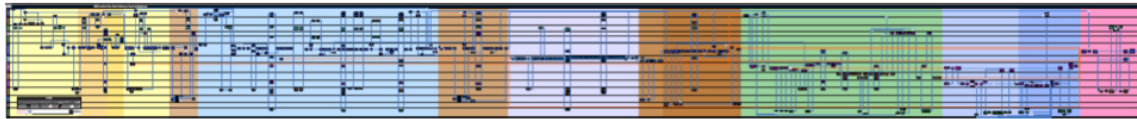
1. Representative Cooperative Oncology Group and Comprehensive Cancer Center

2. Process steps reported only show one loop in the process. Actual development frequently includes multiple loops

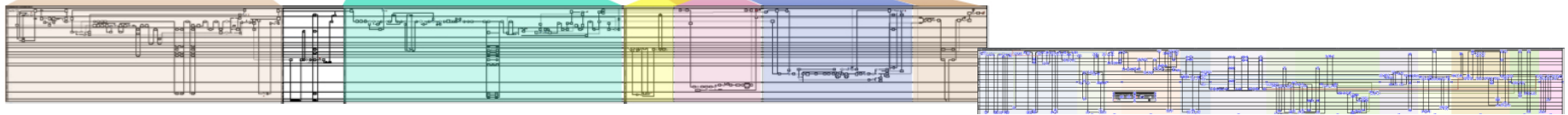
# Total Time to Open a Phase III Cooperative Group Study



Cooperative Group &  
CTEP/CIRB Processes



Comprehensive Cancer  
Center Processes




Median: 784 to 808 days\*  
Range: 435-1604 days

Median: 116 to 252 days\*  
Range: 21-836 days

**Total Median Time from idea to opening~920 days (2.5 years)**  
**Range: 456 – 2440 days (1.25 - 6.7 yrs)**

\* Depending upon site, based on the Phase III trials studied

[illegible]

| AUDIO-VISUAL & MULTI-MEDIA RELEASE FORM                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|
| <p><b>Please read this form in its entirety before signing.</b></p> <p>In consideration for participating in:</p> <p style="text-align: center;"><u>Grand Rounds, December 4, 2005</u></p> <p>A program produced by the Z Cancer Center (ZCC) at ...</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                     |
| <p>1. I authorize ZCC to use any name, likeness, and/or voice in any photograph, film, audiotape, or videotape developed for use in any report, promotional material, or educational program produced by ZCC. This may include, but not be limited to, annual reports, newsletters, brochures, news media coverage, internet and its instant broadcast or presentation.</p> <p>2. This waiver does not constitute the transfer of exclusive rights to ZCC. Simultaneous rights will be retained and may be granted to others.</p> <p>3. My participation in the presentation confers upon me no ownership rights to any materials produced by ZCC. I waive any and all claims to compensation or remuneration of any kind for such use.</p> <p>4. I release ZCC, their producers, their employees, and assigns, from any liability for claims, by me or any other parties, arising out of my participation in the above presentation.</p> | <div style="text-align: right; margin-bottom: 20px;">  </div> <p>_____<br/> <small>DEPUTY DIRECTOR</small></p> <p>David Dahn, PhD</p> <p>_____<br/> <small>PRINT NAME OF PRESIDENT</small></p> <p>401 21<sup>st</sup> Ave S, OGSIN - Vanderbilt University</p> <p>_____<br/> <small>ADDRESS</small></p> <p>Nashville TN 37067</p> <p>_____<br/> <small>CITY STATE ZIP-CODE</small></p> | <p>_____<br/> <small>DATE</small></p> <p>December 1, 2006</p> <p>_____<br/> <small>DATE OF PRESENTATION</small></p> |
| <p style="text-align: center;"><b>AUDIO-VISUAL NEEDS:</b></p> <p style="text-align: right;">_____ 35 mm slides</p> <p style="text-align: right;">_____ <u>SA</u> _____ Perseus/LCD</p> <p style="text-align: right;">I will be bringing my presentation on a _____ CD,</p> <p style="text-align: right;">_____ <u>SA</u> _____ flash drive or _____ my own laptop</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                     |

College of Medicine Continuing Medical Education  
Planning Form for Serial Activities

*(This form and the faculty disclosure form must be completed for EACH serial presentation and submitted to the CME Office PRIOR to the activity)*

Activity Title: \_\_\_\_\_ Grand Rounds \_\_\_\_\_  
Presentation Title: \_\_\_\_\_  
Date of Presentation: \_\_\_\_\_ December 5, 2008 \_\_\_\_\_  
Speaker: \_\_\_\_\_ David Ditt, PhD, MBA \_\_\_\_\_  
\_\_\_\_\_ David Ditt, PhD, MBA, is co-Director of the Center for Management Research in Medicine, Oregon Graduate School of Management and Professor and Director, Engineering Management Program, School of Engineering, Vanderbilt University.  
Address: 401 21<sup>st</sup> Ave S, Nashville, TN  
Office Phone: \_\_\_\_\_ Fax: \_\_\_\_\_  
Topic(s) to be Addressed Time and dates to open oncology clinical trials

Learning Objectives: As a result of participation in this CME activity, physicians will be able to:

1. Understood the time required to open an oncology clinical trial
2. Understood the steps & processes required to open an oncology clinical trial
3. Understood the need to dramatically change the system while both are no longer conducted at US cancer centers.

Faculty Disclosure Form Completed: (Faculty disclosure form must be submitted to the CME Office for each activity regardless of completion) ☒ Yes ☐ No

Will the audience be informed of any significant financial interest or other relationship the speaker may have with a commercial company? ☒ Yes of the following methods MCTB be checked. "Not applicable" is not an option

☐ Verbal Disclosure (you must complete a verbal disclosure form and forward documentation to the presentation)  
☐ Written Disclosure ☒ XXX Slide ☐ Other \_\_\_\_\_  
(Type of written report, slide or other method of disclosure use to document to following presentation)

Has commercial support been provided for this activity? ☒ Yes XXXX No

If yes, list commercial support(s): \_\_\_\_\_  
SPEAKER/ADJUNCT/STUDY/NEEDS XXX CD-Disc for PP Presentation ~ 35 min slides

Please fax completed Planning Form to:  
Curtis Harbison, CMP at (615) 346-3874

**Travel and RV Information Form**  
**PCC Award Rewards**

Name: David M. Olin E-mail Address: david@pyrobricks.com

Emergency Contact \_\_\_\_\_

Address \_\_\_\_\_ Phone #: \_\_\_\_\_

**Airline Transportation**

In order for your award to be added to our 2 Conference account, please call American Express Travel at 800-822-9994 or E-mail [awards@americanexpress.com](mailto:awards@americanexpress.com). Mention you are a Spalder for 2 Grand Rewards. Airlines reservations must be made no later than 30 days prior to the program and will cover [aexp.faa.sba](http://www.aexp.com).

For our records, please advise us of your flight details:

Actual Date/Time: \_\_\_\_\_ Airline/Flight # \_\_\_\_\_

Departure Date/Time: \_\_\_\_\_ Airline/Flight # \_\_\_\_\_

**Ground Transportation**

Round-trip transportation from The International Airport to the Embassy Suites Hotel will be arranged for you and the conference. A driver and car must you [provide the business card # of the airline you traveled on](http://www.embassy.com).

Your car number: \_\_\_\_\_

**Hotel Accommodations:**

Embassy Suites Hotel, 3705 W Blvd,  
Phoenix, AZ, Website: [www.embassysuites.com](http://www.embassysuites.com)

☐ King ☐ 2 Double ☐ Special Requests \_\_\_\_\_

*A confirmation number will be E-mailed to you.*  
*Note: - up to one night is provided by Spalder (additional nights are self-pay).*

I will be traveling: XX Home ☐ Other \_\_\_\_\_

**Photo/Visual Needs:** (Photos will be used in all sections.) Please bring your presentation on flash drive or CD. CD: CD-ROM or .ppt (max) \_\_\_\_\_ Email: [Photo@TravelerConnection.com](mailto:Photo@TravelerConnection.com) CD/Note \_\_\_\_\_

**NOTE:** Please arrive one hour prior to the start of the conference to set up your presentation. Bring a back-up copy of your presentation.

**PLEASE FAX THIS FORM TO: KKK, No Later Than November 7, 2006**

For Questions, Please Call: 777



# AV Requirements

[illegible]

**AUDIO-VISUAL & MULTI-MEDIA RELEASE FORM**

Please read this form in its entirety before signing.

In consideration for participating in:

Grand Rounds, November 5, 2005

A program produced by the Z Cancer Center (ZCC) at ...

I, I authorize ZCC to use my name, likeness, and/or voice in any photograph, film, audiotape, or videotape developed for use in any report, promotional material, or educational program produced by ZCC. This may include, but not be limited to, annual reports, press releases, brochures, news media coverage, internet and its instant broadcast of presentations.

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My participation in the presentation confers upon me no ownership rights to any materials produced by ZCC. I waive any and all claims to compensation or remuneration of any kind for such use.

I release ZCC, their producers, their employees, and assigns, from any liability for claims, by me or any other persons, arising out of my participation in the above presentation.

*David D. Pao*

October 29, 2005

SIGNATURE: \_\_\_\_\_  
David D. Pao

PRINT NAME OF PRESIDENT: \_\_\_\_\_  
REIT NAME OF PRESIDENT: \_\_\_\_\_  
ADDRESS: \_\_\_\_\_  
Nashville TN 37067

DATE OF PRESENTATION: \_\_\_\_\_

**AUDIO-VISUAL NEEDS:**

\_\_\_\_\_ 35 mm slides  
\_\_\_\_\_ 35 mm Perimeter LCD  
I will be bringing my presentation on a \_\_\_\_\_ CD,  
\_\_\_\_\_ 35 mm flash drive or \_\_\_\_\_ my own laptop

**College of Medicine Continuing Medical Education  
Planning Form for Serial Activities**

(This form and its accompanying disclosure form must be completed for each serial presentation and submitted to the CME Office PRIOR to the activity)

Activity Title \_\_\_\_\_  
Session Title \_\_\_\_\_  
Date of Presentation \_\_\_\_\_ December 8, 2008  
Speaker(s) \_\_\_\_\_ David D. Rao, MD, MBA  
\_\_\_\_\_ Assistant Clinical Professor and Co-Director of the Center for Molecular Research in Hematology, Oregon Graduate Science and Professional School, Transportation Management  
\_\_\_\_\_ School of Engineering, Yonderland University  
\_\_\_\_\_ 123456789 314 Ave S, Nashville, TN  
Office Phone \_\_\_\_\_  
Topic(s) to be Addressed Time and steps to open oncology clinical trials  
Learner Objectives: As a result of participation in this continuing medical education you will be able to:  
1. Understood the time required to open an oncology clinical trial.  
2. Understood the steps & process required to open an oncology clinical trial.  
3. Understood the impact to domestically change the system on which are no longer conducted at US cancer centers.  
Faculty Disclosure Form Completed: (Faculty Disclosure Form must be submitted to the CME Office for every activity regardless of commercial support) Yes ☒ No ☐  
How will the audience be informed of any significant financial interest or other relationship the speaker may have with a commercial company? One of the following methods MUST be checked. "Not applicable" is not an option.  
☐ Verbal Disclosure (you must complete a verbal disclosure statement in writing before the presentation)  
☒ Written Material XXX Slide  
(Option of written material, either at the start of the discussion or as follows in presentation)  
Has compensation been provided for this activity? ☒ Yes XXXX  
Yes, list company name(s) \_\_\_\_\_  
**SPEAKER AT DISPOSITIVE SLIDES** XXX CD/Disc for PP presentation ☒ 35 min slides  
Please fill the completed PLANNING FORM to:  
Carla Berube, CMP at (615) 246-0874

**Travel and RV Information Form**  
**ZVC Ground Rounds**

Name: David M. Dills E-mail Address: david@dillsvetbio.edu

Emergency Contact \_\_\_\_\_  
Name \_\_\_\_\_ Phone #: \_\_\_\_\_

**Airline Transportation**

In order for your airfare to be billed to our 2 Conference account, please call American Express Travel at 800-872-9999 or E-mail [amexp@americanexpress.com](mailto:amexp@americanexpress.com). Please let you as a Speaker for 2 Ground Rounds. Airfare Reservations must be made no later than 30 days prior to the program and will cost [www.aet.com](http://www.aet.com).

For our records, please advise us of your flight details:

Arrival Date/Time: Arling/Tight # \_\_\_\_\_  
Departure Date/Time: Arling/Tight # \_\_\_\_\_

**Ground Transportation**

Road/Ship transportation from The International Airport to the Embassy Suites Hotel will be arranged for you and the conference. A driver will meet you [at the Embassy Suites Hotel](http://www.embassy.com) [www.embassy.com](http://www.embassy.com).

Your car number: \_\_\_\_\_

**Hotel Accommodations**

Embassy Suites Hotel, 3701 St. Blvd,  
Phoenix 1, Website: [www.embassysuites.com](http://www.embassysuites.com)  
☐ King ☐ 2 Double ☐ Special Requests \_\_\_\_\_

A confirmation number will be E-mailed to you.  
*Notes - up to one night is provided by NHGRI (additional nights are self-pay).*

I will be staying: ☒ Alone ☐ With: \_\_\_\_\_

**Audio/Visual Needs:** (Downs/Print will be used in all sessions.) Please bring your presentation on flash drive or CD, DVD (HIS \_\_\_ or DVD \_\_\_) ☐ Digital/Screen Connection ☐ Other \_\_\_\_\_

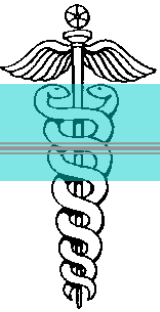
**NOTE:** Please arrive one hour prior to the start of the conference to set up your presentation. Bring a backup copy of your presentation.

**PLEASE FAX THIS FORM TO: xxx, No Later Than November 7, 2006**

For Questions, Please Call: xxx

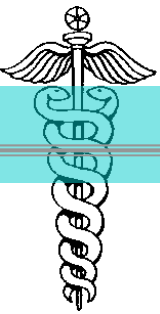
## 2. What are the chances of making a mistake?

# Basic Lessons Learned

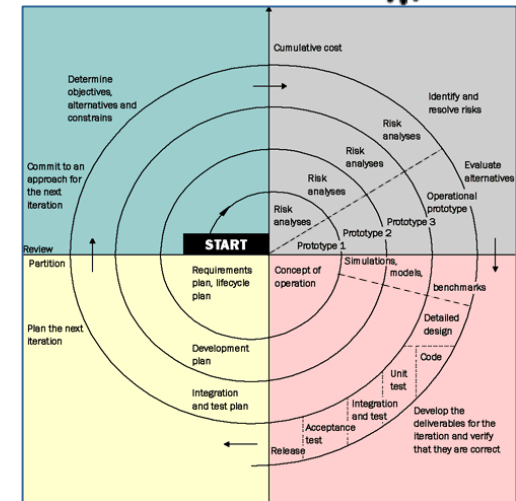
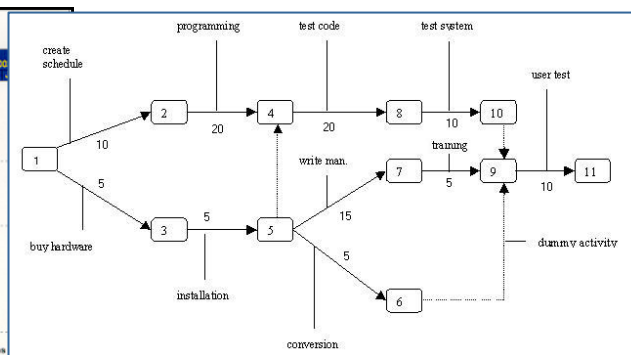
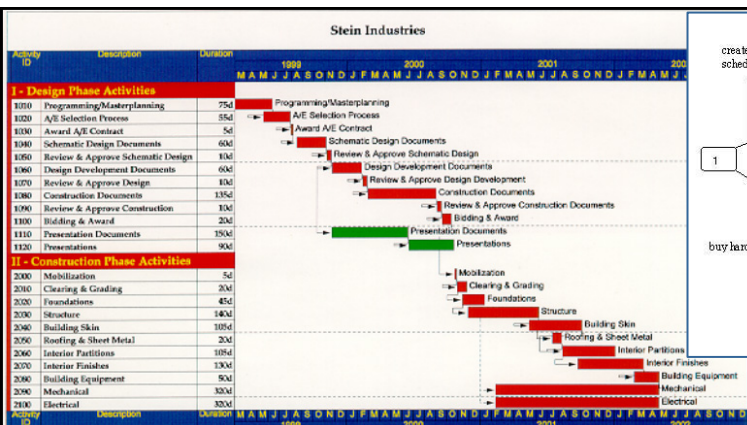


1. **Expectations and environments change constantly**
2. **There is never enough money or resources**
3. **Using a pathway can make life easier**
4. **Use experts when every possible but remember: they don't know your domain**

# The Project Management Institute



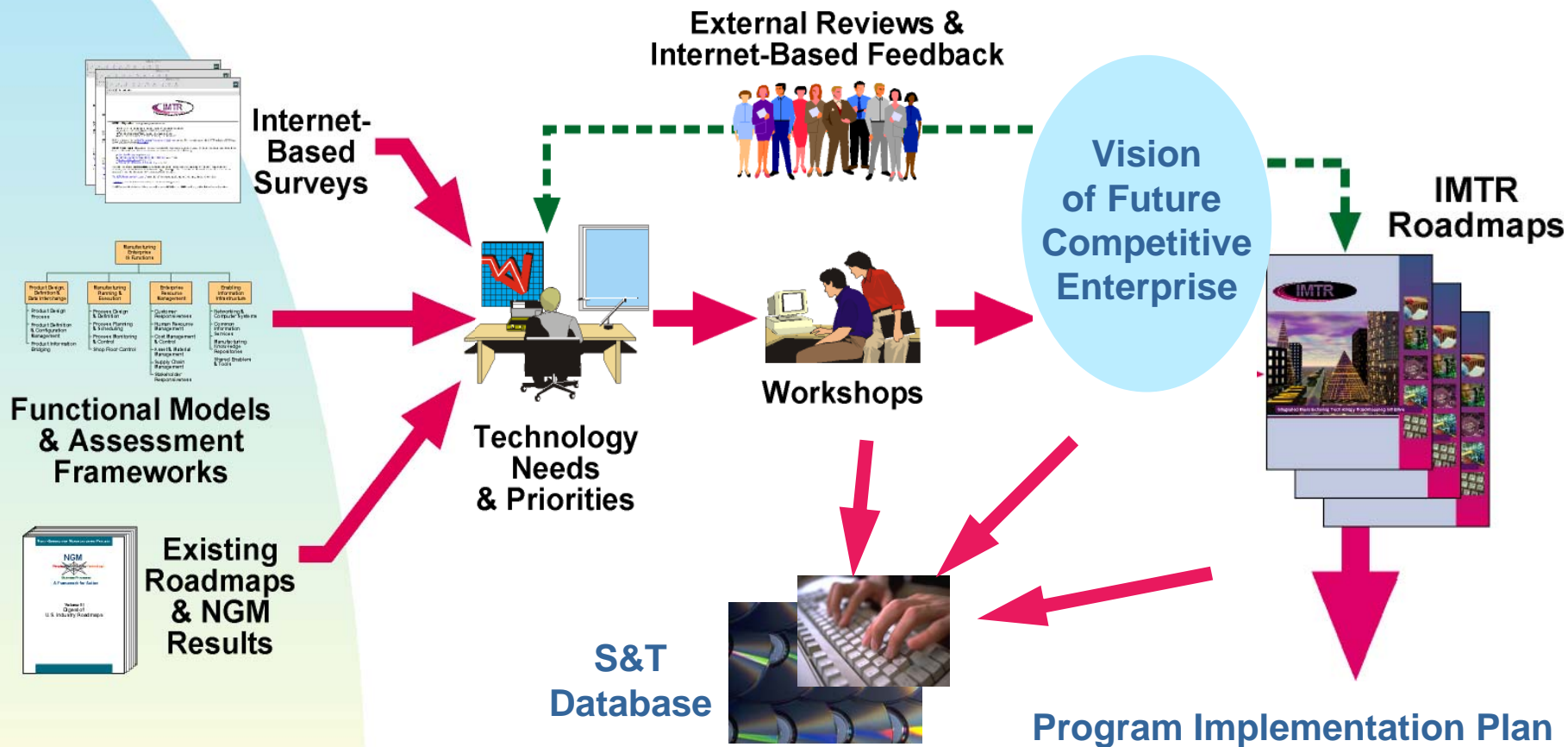
- Proven tools and techniques for converting ideas in to reality
- Certification programs
  - [www.pmi.org](http://www.pmi.org)



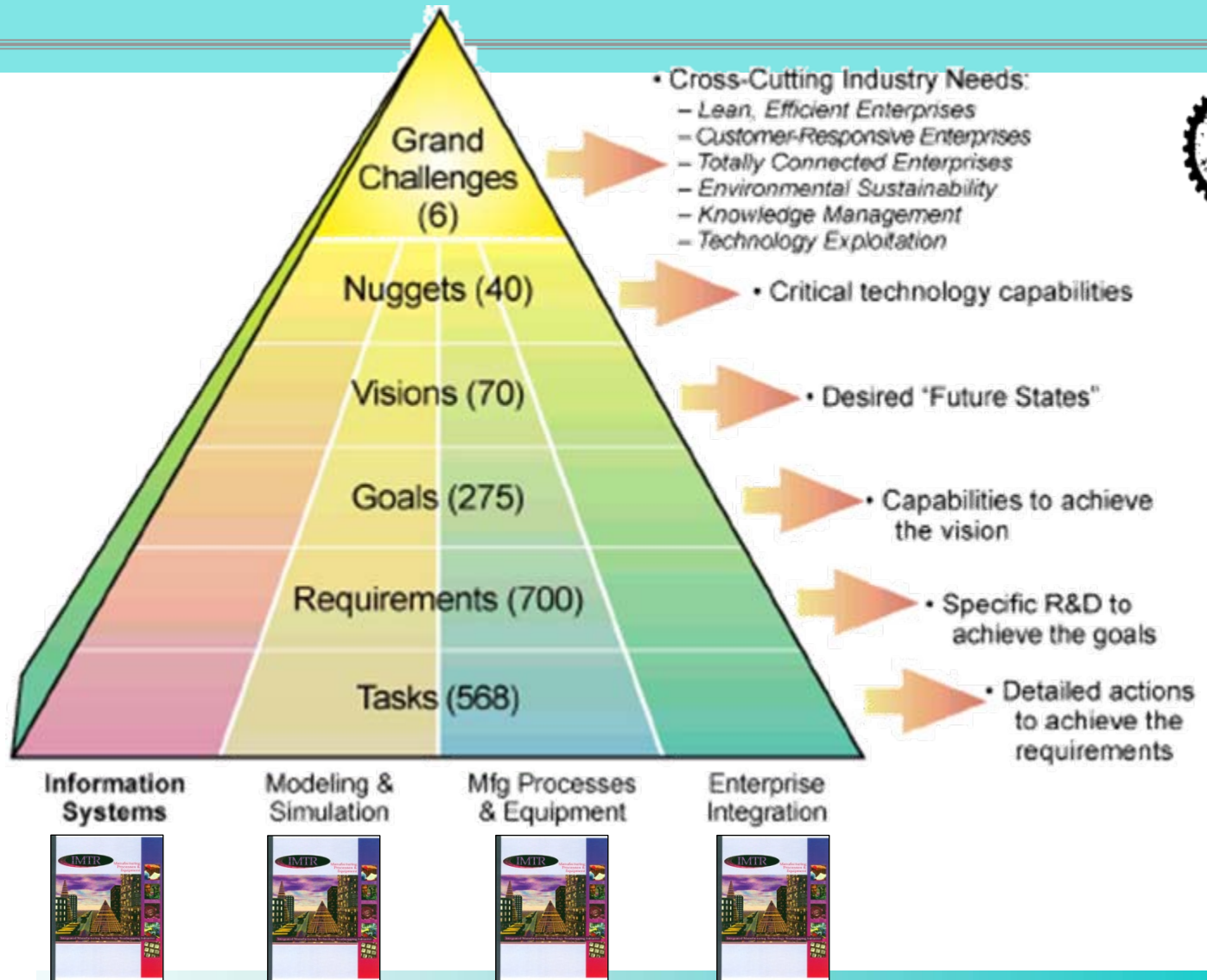
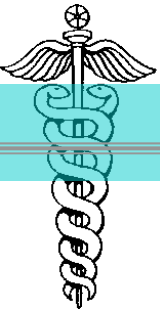
# One Roadmap Example: Integrated Manufacturing Technology Initiative

Source: <http://www.imti21.org/>

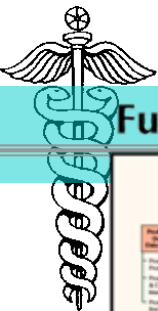
*Over 300 people from 150 companies participated  
in the roadmapping process*



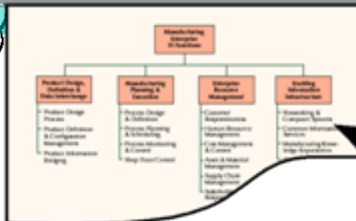
# IMTI Solutions



# IMTI Deliverables

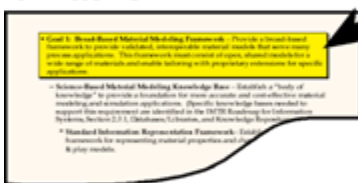


## Functional Model



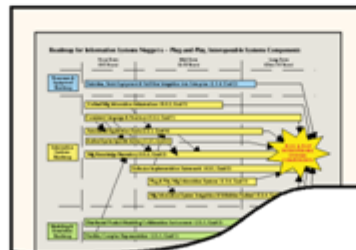
Decomposes the technology area into logical functions of a "generic" manufacturing enterprise

## Goals, Requirements, & Tasks



Define the desired "future state," the capabilities needed to attain it, and the R&D to attain each capability

## "Nugget" Roadmaps



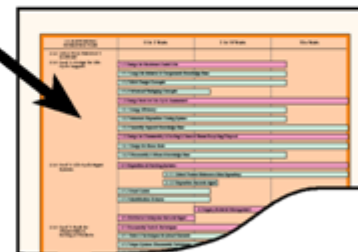
Identify "Top 10" capabilities to be delivered, and tie in contributing technologies from all four IMTR roadmaps

## Current State Assessment & Future State Vision



Baseline where we are today, and where we want to be

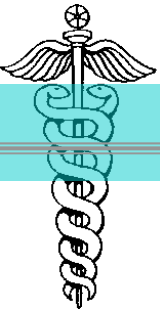
## Milestone Plans



Define a timeframe for accomplishing the goals, requirements, and tasks; a basis for detailed R&D plans



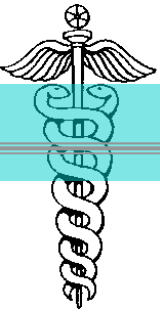
# Remember



- **Don't confuse the tool with the philosophy**
  - **Jidoka and Andon cords & lights**

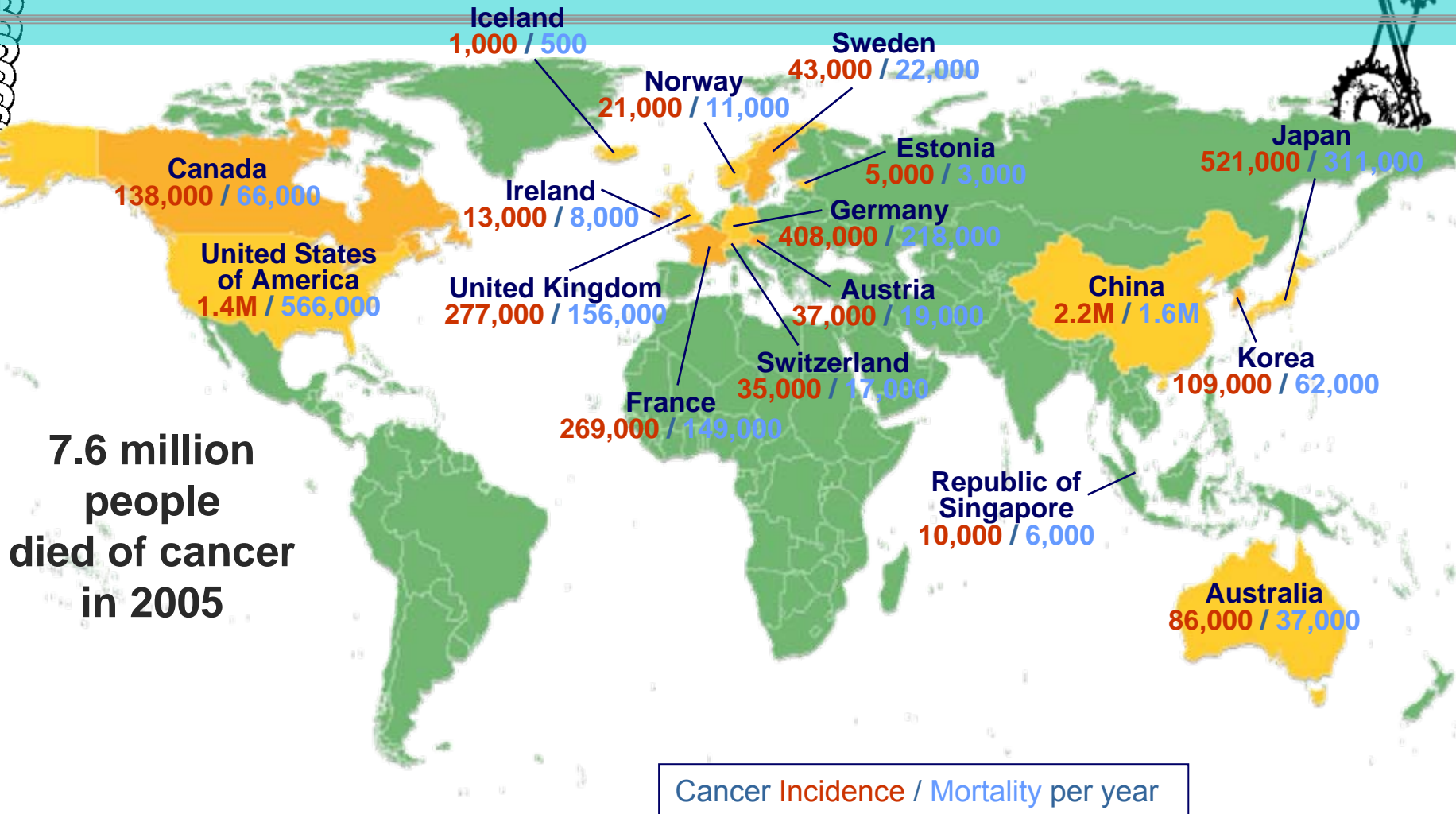
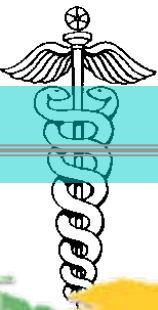


# Basic Lessons Learned



- 1. Expectations and environments change constantly**
- 2. There is never enough money or resources**
  - So they need to be used wisely
  - Priorities will be set
    - The only question is: will you help set them?
- 3. Using a pathway can make life easier**
  - Good pathways/processes can show you things you never expected & can be trend setting
  - *But pathways are living documents that can grow in unexpected ways*
- 4. Use experts when every possible but remember: they don't know your domain**

# Importance of the Problem: the Cancer Burden



Source: Derived from International Agency for Research on Cancer, GLOBOCAN 2002 database



**“Those who do not learn from history are doomed to repeat it”**  
- George Santayana

**“We didn’t get to be this smart because we were this smart”**  
- Frank Tidaback

**“Unless a decision has ‘degenerated into work’ it is not a decision; it is at best a good intention.”**  
-- Peter Drucker

**“You’re in it for yourself, but not by yourself.”**  
-- Ray Kroc



Thank you

[www.cMRHc.org](http://www.cMRHc.org)